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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,014

07/31/2003

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MA9606P

9368

7590 05/13/2009
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EXAMINER

SOROUGH, ALI

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

05/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,014	Applicant(s) CALHOUN ET AL.	
	Examiner ALI SOROUGH	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 34-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/06/2009 has been entered.

Status of the Claims

Claim 1 is currently amended and claims 30-33 and 37-51 are cancelled. Therefore, claims 1-29 and 34-36 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The rejection of claims 1, 2, 4, 5, 14-17, 21, 22, 34-36, and 51 under 35 U.S.C. 102(b) as being anticipated by Arm et al (WO 93/20859, published 10/28/1993) **is maintained.**

Arm et al. teaches, "biodegradable films comprising a polylactic/polyglycolic acid copolymer, a therapeutically effective amount of polypeptide growth factor, and a carrier are provided." (See abstract). "Compositions are in the form of biodegradable polyester films, such as polylactic acid, polyglycolic acid ..." (See page 5, Lines 12-13). "Because polymers of enantiomeric lactides are crystalline and therefore more resistant to degradation than their racemic counterparts, it is preferred to use mixed enantiomer (e.g. poly (D, L-lactide acid)) polymers within the present invention." (See page 6, Lines 19-23). "Film thickness of less than about 50 μm are preferred, particularly film thickness between 5 and 20 μm ." (See page 6, Lines 33-35). "The films may be affixed to the outer surface of an implantable or prosthetic device such as a screw, pin, plate, rod or artificial joint component." (See abstract). Arm et al. teaches the use of the film with non-biological implants such as a medical device, i.e. "rods" for "enhancing bone repair of bone fractures" (see abstract) and also with biological implants such as an allograft material, i.e. "demineralized bone matrix plugs" to induce new bone formation. "The films may, for example, be wrapped around the outer surfaces of surgical screws, rods, pins, plates, and the like. The films can also be used to coat bone filling materials, such as hydroxyapatite blocks, demineralized bone matrix plugs, collagen matrices and the like ..." (See page 13, Lines 9-19). With regard to resorbability of the film Arm et al. teaches, "the unloaded *in vitro* degradation study showed mass loss from 50:50 and

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85:15 PLA/PGA copolymer rods in the range of 80-95% by the 76-day point ..." (See page 15, Lines 25-27). With regard to the film characteristic being nonporous although Arm et al. is silent to this because the film has the same characteristic composition therefore products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. Therefore, it is the examiners position that the film taught by Arm et al. would be nonporous for the reasons above. Arm et al. teaches a film of 100% polylactic acid and the addition of a carrier and peptide growth factor are a preferred embodiment but not a limiting embodiment of Arm et al.'s invention. (See page 3, Lines 36-37 and page 4, Lines 1-8).

Response to Applicant's Arguments

Applicant argues that Arm et al. teach the membrane is placed only in rabbits and not humans. Applicant's arguments have been fully considered but found not to be persuasive. It is the Examiners position that the membranes taught by Arm et al. are taught to be useful in humans but are tested in rabbits. Therefore, the membranes are expected to work equally well in humans as well as in rabbits.

Applicant further argues that Arm et al. does not disclose a nonporous film. Applicant's argument has been fully considered but found not to be persuasive. It is the Examiners position that the 100% polylactide film disclosed by Arm et al. would inherently be nonporous since it is structurally indistinguishable from the instantly claimed film.

Applicant also argues that Arm et al. is directed to films that promote tissue in-growth and therefore teach away from the instantly claimed tissue adhesion attenuating method. It is the Examiners position that the control film used in Arm et al. would necessarily attenuate adhesion of tissue since all the other embodiments taught by Arm et al. are directed to promoting tissue in-growth. It should also be noted that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Therefore, for the foregoing reasons, the rejection of claims 1, 2, 4, 5, 14-17, 21, 22, 34-36, and 51 under 35 U.S.C. 102(b) is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. The rejection of claims 1, 3, 4, 5, 21-28, and 51 under 35 U.S.C. 103 (a) as being unpatentable over Ledergerber (US Patent 4955907, Published 09/11/1990) in view of Schneider (US Patent 3636956, Published 01/25/1972) **is maintained**.

Applicant Claims

Applicant claims a method for attenuating adhesion between an implant (i.e. organ) and surrounding tissue providing a non-porous, resorbable planar membrane polymer of poly-L-lactide and poly-D-L-lactide surrounding an implant.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Ledergerber teaches, "the present invention is directed to: (A) the use of a covering for a prosthesis ... Expanded PTFE (polytetrafluoroethylene) is used in the preferred embodiment of this invention." (See column 2, Lines 66-68 and column 3, Lines 1-4). "The implant coverings usable in connection with this invention may be manufactured from any material which promotes limited tissue ingrowth into the

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material, and has biocompatibility and low reactivity and disorganizes scar tissue at the implant/body interface." (See column 6, Lines 57-62). "Implantable prosthetic devices have been used in numerous locations in the body. The most common breast prosthesis is ... in which there is an elastomeric container, typically silicone, which is filled with soft gel, typically silicone gel or a saline solution or combination of both. It is known that when a prosthetic device ... is implanted in the body (see column 1, Line 10), the fibrous scar tissue encapsulates the device." (See column 1, Lines 12-25). Ledergerber further teaches that PTFE is "available in sheet form of various thicknesses ..." (See column 7, Lines 1-2). Ledergerber also teaches that PTFE maybe applied to the prosthesis by a complex expandable weave. (See column 7, Lines 17-23).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Ledergerber lacks a teaching wherein the covering consists essentially of a lactide polymer or a copolymer of two or more cyclic esters. This deficiency is cured by the teachings of Schneider.

Schneider teaches a product "absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body comprising an orineted synthetic polylactide polymer ..." (See column 14, claim 1). "The polylactide polymer is poly L(-) lactide containing upto 15 percent by weight of repeating units derived from DL-lactide." (See column 15, claim 4). "Instead of spinning the polylactide polymers into filaments, it is possible to extrude or cast it into films ..." (See column 6, Lines 59-60). "The products of the invention are useful in surgical applications ..." (See column 14,

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Lines 47-48). The product used as sutures showed "tissue reaction was minimal to absent with no evidence of granuloma formation and adhesion." (See column 8, Lines 65-68). It was also shown that the use of the product showed less scar tissue than did catgut. (See column 8, Lines 72-75).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention, to combine the teachings of Ledergerber with Schneider. One would have been motivated to do so because Ledergerber teaches that any material that impedes tissue in-growth and reduces scarring, can be used as a covering with the invention of Ledergerber. One would further be motivated to use the film of Schneider because the film taught by Schneider is biosorbable. For the foregoing reasons, the instantly claimed method of attenuating adhesions between an implant and surrounding tissue is rendered obvious.

Response to Applicant's Arguments

Applicant argues that Ledergerber does not teach a nonporous film covering or a method of attenuating tissue ingrowth. Applicant's arguments have been fully considered but found not to be persuasive. The Examiner has not relied on Ledergerber for providing nonporous film; this deficiency is cured by the teachings of Schneider. Ledergerber does in fact teach limiting tissue ingrowth for the purposes of reducing scar tissue formation and therefore it is the Examiners position that this teaching reads on the limitation "attenuating adhesions between the implant and surrounding tissue".

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Applicant further argues that Schneider does not teach a film for application but only teach the formation of filaments. Applicant's arguments have been fully considered but not found to be persuasive. Schneider teach that films can be formed and it would have been obvious to one of ordinary skill in the art to use the composition taught by Schneider in a variety of different conformations for use in surgical applications. Both Ledergerber and Schneider are directed to limiting tissue ingrowth associated with the material and thereby reducing scarring when the materials are used. Therefore, because both inventions are directed to achieving the same problem it would have been obvious to one of ordinary skill in the art to use film made of the same material used in the sutures of Schneider to cover the implant of Ledergerber. Therefore, the rejection of claims 1, 3, 4, 5, 21-28, and 51 under 35 U.S.C. 103 (a) is maintained.

2. The rejection of claim 6 under 35 U.S.C. 103 (a) as being unpatentable over Ledergerber (US Patent 4955907, Published 09/11/1990) in view of Schneider (US Patent 3636956, Published 01/25/1972) further in view of Vijayan et al. (US Patent 5047054, Published 0/10/1991) **is maintained**.

Applicant Claims

Applicant claims a method for attenuating adhesion between an implant (i.e. organ) and surrounding tissue providing a non-porous, resorbable planar membrane polymer of poly-L-lactide and poly-D-L-lactide surrounding an implant.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The combined teachings of Ledergerber and Schneider are discussed above

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***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Ledergerber and Schneider lacks a teaching wherein the covering is heat shrunk on the implant. This deficiency is cured by the teachings of Vijayan et al..

Vijayan et al. teach an orthopedic implant having a thin coating that is applied by a variety of means. The coat is then subjected to heat treatment to allow the coat to cure and provide a tightly adherent biocompatible coating over the implant. (See column 3, Lines 11-22).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention, to combine the teachings of Ledergerber and Schneider with Vijayan et al. One would have been motivated to do so because heating the coating after applying it to the implant would provide for a tightly adherent coating. For the foregoing reasons, the instantly claimed method of attenuating adhesions between an implant and surrounding tissue is rendered obvious.

Response to Applicant's Arguments

Applicant reiterates arguments from above. Since those arguments have been addressed previously they will not be discussed again here. Therefore, the rejection of claim 6 under 35 U.S.C. 103 (a) is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

3. Claims 1, 4, 7-18, 21, and 22 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Hossainy et al. (US 6541373, published 09/17/2002, Filed 08/04/2000).

Applicant Claims

Applicant claims a method for attenuating adhesion between an implant and surrounding tissue providing a non-porous, resorbable planar membrane polymer of poly-L-lactide and poly-D-L-lactide surrounding a biological or non-biological implant.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Hossainy et al teaches, a “method of forming a therapeutic coating onto a surface of an implantable prosthesis” (See title). Examples of implantable devices “include self-expandable stents, balloon-expandable stents, and grafts, among other possibilities”. (See column 3, Lines 39-40). An example of a graft taught by Hossainy et al. is a vascular graft. (See column 4, Line 12). “The graft may be attached at each end of the diseased region ... alternatively the diseased region maybe removed and replaced by the graft.” Hossainy et al. further teaches, “ In accordance with some

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embodiments, a predetermined amount of therapeutic substance is added to predetermined amount of first fluid.” (See column 3, Lines 64-66). “Exemplary first fluids include, but are not limited to, deionized water, methanol, ethanol, reon, and acetonitrile. In some other embodiments, the composition additionally includes a polymer, or combination of polymers, dissolved in the first fluid. Example of biosorbable materials include but are not limited to polycaprolactone (PCL), poly-D,L-lactide, poly-L-lactic acid (L-PLA) ...” (See column 5 Lines 46-62). “In such embodiments, the polymeric materials can make up from about 0.1% to about 30%, or more particularly from about 0.1% to about 10% by weight of the total weight of the composition...” (See column 6, Lines 14-16). An example method of coating a implantable prosthesis is taught by Hosseiny et al. “A ... ethylene vinyl alcohol copolymer:DMSO solution is made ... Actinomycin is added to the EVOH:DMSO solution to form a suspension. Pluronic, a suspension stabilizer is added to the suspension ... The ... stent is attached to mandrel wires and dipped into the suspension. The coated stent is then placed in a vacuum oven ...” (See column 11, Lines 39-55). Following application of the composition to the prosthesis removal of the first fluid techniques such as “evaporation at ambient pressure and room temperature in an anhydrous atmosphere for 48 hours, or exposure to mild heat, e.g. 60-65°C, under vacuum conditions” is used (column 8, Lines 4-7). In variations of the application of the composition to the surface of the prosthesis Hossainy et al. teaches, “spraying the composition onto the prosthesis or immersing the prosthesis in the composition.” (See column 7, Lines 48-49).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Hossainy et al. does not anticipate the instant invention but they do teach a class of polymers from which polylactic acid and more specifically poly-L-lactic acid and poly-D, L-lactic acid can be selected. Further, Hossainy et al. teach a class of first fluids (solvents) from which acetonitrile can be selected. Hossainy et al. thereby teach the combination of the polymer and solvent of the instant invention. Although a drying step using a vacuum oven is not anticipated by Hossainy et al., the teaching of EVOH:DMSO would lead one skilled in art to use the same method steps of coating an implant and drying using a vacuum oven with a solution of polylactic acid: acetonitrile.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

In the example method taught by Hossainy et al. for coating an implantable prosthesis, the EVOH could be replaced with a lactic polymer as this is given as a suitable substitute polymer, and DMSO can be replaced with acetonitrile as Hossainy et al lists this as suitable first fluid substitute. Therefore, any combination of polymer to first fluid (solvent) composition disclosed in Hossainy et al. can reasonably be dried using a vacuum oven or under anhydrous atmosphere, under room temperature conditions. An anhydrous atmosphere, being simply air with the moisture removed, would make obvious the use of both evaporation techniques concurrently. Since both drying by air and vacuum oven cause the solvent to evaporate from the composition after the composition is applied to the implant, the combination of both techniques would be obvious because it would enhance the evaporation of the solvent. One would be motivated to use polylactides because a polylactide, such as poly-D,L-lactide, is

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more available to degradation. It is noted that actinomycin is compound that inhibits cell proliferation and therefore it is the examiners position that a film comprising such a compound would in fact impede adhesion between the surrounding tissue and the implant absent evidence that the compound would materially affect the basic and novel characteristic of the instantly claimed invention. For the foregoing reasons, the instantly claimed method of attenuating adhesions between an implant and surrounding tissue is rendered obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616